

Meiji Seika Pharma Co., Ltd.

October 21, 2024

CHMP Adopts Positive Opinion Recommending Approval of IMULDOSA[®], a Biosimilar Referencing STELARA[®]

Meiji Seika Pharma Co., Ltd. (Headquarters: Tokyo, Japan, President and Representative Director: Daikichiro Kobayashi) announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopts positive opinion recommending approval of IMULDOSA[®] (development code: DMB-3115), a biosimilar referencing STELARA[®] (ustekinumab) which is marketed by Janssen Biotech Inc., a subsidiary of Johnson & Johnson.

IMULDOSA[®] was developed in collaboration with Dong-A ST Co., Ltd. (Headquarters: Seoul, South Korea, President and CEO: Jaehun Jung). The Marketing Authorization Application (MAA) was submitted by Accord Healthcare Limited, specialty division of Intas Pharmaceuticals Ltd. (Headquarters: Ahmedabad, India, Executive Chairman & Managing Director: Binish Chudgar), to which IMULDOSA[®] has been licensed. IMULDOSA[®] will be marketed in the EU by Accord Healthcare Limited.

IMULDOSA[®] is a recombinant monoclonal antibody approved for the treatment of patients with several autoimmune diseases. Meiji Seika Pharma is positioning IMULDOSA[®] as a global strategic product and is promoting global development jointly with Dong-A ST. The worldwide distribution rights, excluding Japan, South Korea, and certain Asian regions, were licensed to Intas Pharmaceuticals in July 2021.

Meiji Seika Pharma strives to promote the spread of biopharmaceuticals and contribute to medical care and public health, through the development and commercial supply of high-quality biosimilars with low economic burden.